

## 510(k) SUMMARY

### I. GENERAL INFORMATION:

#### Establishment:

- Address: Siemens Medical Systems, Inc.  
186 Wood Avenue South  
Iselin, NJ. 08830
- Registration Number: 2240869
- Contact Person: Kathleen Rutherford  
Manager, Regulatory Submissions  
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#### Date of Summary Preparation:

#### Device Name:

- Trade Name: Siregraph CF
- Common Name: Remote Multi-functional Overtable  
X-ray Diagnostic System
- Classification Name: Image Intensified Fluoroscopic X-ray System
- Classification: Class II

#### Performance Standards:

21 CFR, Subchapter J

All system components to which the above standard applies are certified to conform with 21 CFR subchapter J

### II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION.

#### Device Description:

The Siemens Siregraph CF is a multifunctional, overtable X-ray diagnostic system that was developed for remote examinations. The Siregraph CF has a motorized table tilt from +90° to -18°. The Siregraph CF X-ray tube/spot film system is equipped with a motorized telescoping arm which can be extended to a maximum SID of 150 cm. The x-ray tube/spot film device can be programmed to perform linear tomography (planigraphy) at three different angles; 40° with a tomographic range of 113 cm, 20° with a tomographic range of 131 cm and 8° with a tomographic range of 142 cm. In addition to the overtable tube the Siregraph CF can be configured with an overhead tube support for exposures using Bucky Wall Stand.

**Siemens Medical Systems, Inc.**

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# SIEMENS

## Intended Use:

The Siemens Siregraph CF is a remote overtable radiographic/fluoroscopic x-ray diagnostic system that was designed for universal implementation in the hospital and clinical environment. The Siregraph CF, remote X-ray system, has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examinations of the urinary tract, lymphography, myelography, venography, arthrography angiography and DSA.

## Technological Characteristics:

The Siregraph CF is not a stand alone device, but functions as a platform for specific X-ray components (image intensifier, X-ray tube and housing, spotfilm device, Bucky Wall stand, collimator, generator, etc.) and television systems (Videomed DI and Videomed SX) to create a flexible remote radiographic/fluoroscopic x-ray system.

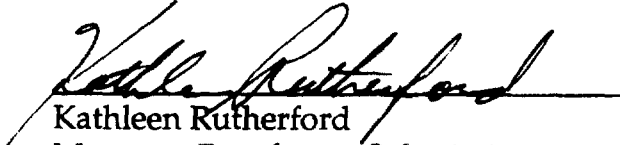
## General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling and the information provided will enable the user to operate the device in a safe and efficacious manner. Several safety features including visual and audible warnings are incorporated into the system design. Furthermore, Siregraph CF is continually monitored, and if an error occurs, the system function will be blocked and an error message displayed. The operators of this generator are trained health care professionals familiar with and responsible for the X-ray studies to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

## Substantial Equivalence:

The Siregraph CF remote Radiographic/fluoroscopic X-ray diagnostic system for universal implementation in radiographic/fluoroscopic procedures, and the subject of this premarket notification, is substantially equivalent to the following medical devices currently in commercial distribution.

Model	Company	FDA K-Number
Sireskop SX	Siemens Medical Systems, Inc.	K951358
Prestilix 1600X	GE Medical Systems	K924310
Diagnost 96	Philip Medical Systems	K912470

  
Kathleen Rutherford  
Manager, Regulatory Submissions

1/16/96  
Date